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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
07/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/008,955	KLINGEMANN, HANS	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-19,21,23-25,28,29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22,26,27,30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

1. In view of the Brief filed on 3/23/10, PROSECUTION IS HEREBY REOPENED. As set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

2. Claims 20,22,26,27,30 are under consideration.

3. The substitute specification filed 10/05/07 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because it contains new matter.

The added material which is not supported by the original disclosure is as follows. The first line of the abstract constitutes new matter in that it lacks further limitations that were originally included with said statement (aka Additionally, the invention provides an NK-92 cell, or an NK-92 cell modified by transfection with a vector conferring advantageous properties, which is unable to proliferate and which preserves effective cytotoxic activity). Regarding the last line of the abstract, the specification discloses NK-92 cell line transfected with a vector encoding mutant B2 microglobulin as per page 20 of the specification but does not disclose the scope of the last line of the abstract which encompasses transfection with normal B2 microglobulin.

The recitation of "which are incorporated herein by reference in their entirety" in page 1 also constitutes new matter.

It is also noted that the substitute specification contains blank numbered pages not found in the original specification wherein said blank pages should not be present.

4. The amendment filed 10/15/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows.
The first line of the abstract constitutes new matter in that it lacks further limitations that were originally included with said statement (aka Additionally, the invention provides an NK-92 cell, or an NK-92 cell modified by transfection with a vector conferring advantageous properties, which is unable to proliferate and which preserves effective cytotoxic activity). Regarding the last line of the abstract, the specification discloses NK-92 cell line transfected with a vector encoding mutant B2 microglobulin as per page 20 of the specification but does not disclose the scope of the last line of the abstract which encompasses transfection with normal B2 microglobulin.

Applicant is required to cancel the new matter in the reply to this Office Action.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 20,22,26,27,30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30-35,46,48,50,53 of copending Application No. 10/701,359. Although the conflicting claims are not identical, they are not patentably distinct from each other because whilst the two sets of claims differ in scope, both sets of claims encompass in vivo treatment of tumors with NK-92 and cytokine. The NK-92 cells are administered by injection (encompasses intravenous). IL-2 is a cytokine with the property of claim 27. The tumors of claim 23 are art known forms of tumors and are "non-solid". The tumor of claim 32 is solid (only solid tumors could receive intratumor injection).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has indicated that a TD will be filed upon the recognition of otherwise allowable subject matter.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 20,22,26,27,30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method wherein the disease treated is cancer and wherein the cancer cells can be lysed/recognized by NK-92, does not reasonably provide enablement for the claimed method of treating a "pathology" wherein said "pathology" could encompass any disease (for example autoimmune disease) including diseases wherein the disease was caused by cells that could not be lysed/recognized by NK-92 cells. The specification does not enable any person skilled in the art to which

it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

predictability or unpredictability of the art, and (8) the breadth of the claims. Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

Regarding Wands factors 4,5,7,8 the claimed methods encompass treating a "pathology" wherein said "pathology" could encompass any disease (for example autoimmune disease) including diseases wherein the disease was caused by cells that could not be lysed/recognized by NK-92 cells. Regarding autoimmune diseases, there is no evidence supplied in the specification that NK-92 cells can lyse cells which cause autoimmune diseases. Regarding cancer cells, Gong et al. disclose that whilst NK-92 cells can lyse certain cancer cell lines, there are cancer cells that are resistant to lysis by NK-92 cells (for example see Figure 4, SR-91 tumor cells). Thus, the state of the art is that it is highly unpredictable whether the claimed invention could be used to treat autoimmune disease or cancers that contained tumors or effector cells that were not lysed/recognized by NK-92 cells. As per Wands factor (8), the claims encompass the treatment of "pathology" wherein said "pathology" could encompass any disease (for example autoimmune disease) or diseases wherein the disease was caused by cells that could not be lysed/recognized by NK-92 cells.

Regarding Wands factors 1-3, the specification discloses experimental data from in vitro assays regarding the use of said cells to lyse specific target cell lines. However, the claimed methods encompass treating a "pathology" wherein said "pathology" could encompass any disease (for example autoimmune disease) and/or diseases wherein the disease was caused by cells that could not be lysed/recognized by NK-92 cells. Regarding autoimmune diseases, there is no evidence supplied in the specification that NK-92 cells can lyse cells which cause autoimmune diseases. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.).

It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 20,22,26,27,30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al. in view of Santoli et al. (US Patent 5,272,082). Applicants arguments have been considered and deemed not persuasive.

Gong et al. teach use of NK-92 cells to lyse leukemic tumor cells (see Materials and Methods section and page 654, second column). Gong et al. teach that said cells require IL-2 to function (see page 658, first column). Gong et al. does not in vivo use of NK-92 cells to treat cancer. Santoli et al. teach that lytic human derived cell lines can be used in vivo to treat disease or in preclinical in vivo studies(see column 10). Santoli et al. teach that said cells are injected iv(see column 10, penultimate paragraph) wherein injection utilizes a syringe and wherein the injected NK-92 cells would be adjacent to leukemic cells in the blood. Santoli et al. disclose that the cells can be administered with the cytokine IL-2 (see column 7, third paragraph). Santoli et al. teach that said cells can be modified to bind solid tumors (see column 7, last paragraph, continued on next column). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Gong et al. teach use of NK-92 cells to lyse tumor cells, while Santoli et al. teach in vivo use of cytotoxic cell lines. One of ordinary skill in the art would have been motivated to do so because Santoli et al. teach that lytic human derived cell lines can be used in vivo to treat disease or in preclinical in vivo studies(see column 10).

Regarding applicants comments and the Klingemann declaration, Santoli et al. teach that lytic human derived cell lines can be used in vivo to treat disease whilst Gong et al. disclose that NK-92 cells are a lytic human derived cell line. In addition, as per the specification, page 2, last paragraph, use of NK cells and LAK cells to treat cancer in vivo was already known in the art. Gong et al. disclose that *the NK-92 cell line displays characteristics of NK cells* (see abstract), *wherein use of NK cells to treat cancer in vivo*

was already known in the art. Furthermore, in the post KSR Int'l Co. v. Teleflex Inc. universe, motivation per se is not even required in a rejection under 35 USC 103. In KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

In the instant rejection, NK-92 cells were known in the art as was use of human derived cell lines to treat disease. In addition, as per the specification, page 2, last paragraph, use of NK cells to treat cancer in vivo was already known in the art whilst Gong et al. disclose that the NK-92 cell line displays characteristics of NK cells.

Regarding applicants comments about the differences between said cells and those taught by Santoli et al., Gong et al. teach methods for growing and maintaining said cells (see page 654, first column). While the two types of cells differ in phenotype, both the cells described by Santoli et al. and NK-92 are lytic human derived cell lines that can lyse various tumor cells. Santoli et al. teach that lytic human derived cell lines can be used in vivo to treat disease or in preclinical in vivo studies(see column 10). In addition, the use of NK cells to treat cancer in vivo was already known in the art whilst Gong et al. disclose that the NK-92 cell line displays characteristics of NK cells. Regarding applicants' comments about Gong et al., there is no teaching in Gong et al. that NK-92 cells are unacceptable for in vivo use. Regarding applicants comments about Santoli et al., Santoli et al. disclose that there is a need for therapeutic methods for treating cancers using cytotoxic cell lines because said cell lines avoid the need to produce LAK cells derived from the particular patient (see column 2, second paragraph). In addition, the use of NK cells to treat cancer in vivo was already known in the art whilst Gong et al. disclose that the NK-92 cell line displays characteristics of NK cells. Furthermore, NK-92 cells could be used in patients that contained tumor cells that were not lysed by TALL cells. As per stated above, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**.

Regarding applicants comments, the MPEP section 2121 states:

2121 [R-6] Prior Art; General Level of Operability Required to Make a Prima Facie Case

I. >< PRIOR ART IS PRESUMED TO BE OPERABLE/ENABLING

When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

The MPEP section 2143.02 states:

2143.02 [R-6] Reasonable Expectation of Success Is Required

>A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. KSR International Co. v. Teleflex Inc., 550 U.S 82 USPQ2d 1385, 1395 (2007); Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson 's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

I. < OBVIOUSNESS REQUIRES ONLY A REASONABLE EXPECTATION OF SUCCESS

The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (Claims directed to a method of treating depression with amitriptyline (or nontoxic salts thereof) were rejected as prima facie obvious over prior art disclosures that amitriptyline is a compound known to possess psychotropic properties and that imipramine is a structurally similar psychotropic compound known to possess antidepressive properties, in view of prior art suggesting the aforementioned compounds would be expected to have similar activity because the

structural difference between the compounds involves a known bioisosteric replacement and because a research paper comparing the pharmacological properties of these two compounds suggested clinical testing of amitriptyline as an antidepressant. The court sustained the rejection, finding that the teachings of the prior art provide a sufficient basis for a reasonable expectation of success.); Ex parte Blanc, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Claims were directed to a process of sterilizing a polyolefinic composition with high-energy radiation in the presence of a phenolic polyester antioxidant to inhibit discoloration or degradation of the polyolefin. Appellant argued that it is unpredictable whether a particular antioxidant will solve the problem of discoloration or degradation. However, the Board found that because the prior art taught that appellant's preferred antioxidant is very efficient and provides better results compared with other prior art antioxidants, there would have been a reasonable expectation of success.).

Regarding applicants comments, the evidence of record does not establish that the prior was not enabled. Furthermore as per above, obviousness requires only a reasonable expectation of success. Regarding the Klingemann declaration, Santoli et al. teach that there is a need for cytotoxic cell lines which could be used to treat cancer (see column 2, second paragraph). In view of the high level of skill in the art (Ph.D. or MD, with extensive research training) it would have been obvious to a routineer that other cytotoxic cell lines could be potentially used as per Santoli et al. In addition, the use of NK cells to treat cancer in vivo was already known in the art whilst Gong et al. disclose that the NK-92 cell line displays characteristics of NK cells.
Regarding comments in the Klingemann declarations about differences between NK-92 cells and TALL 104 cells, Tam et al. (Human Gene therapy, 1999) (reference 124 on the Klingemann declaration, page 22), page 1369 states that:
"An alternative is to use established cytotoxic NK tumor cell lines, which would give access to large numbers of effector cells. This concept has been proved by Cesano et al. (1997), who showed that ***an NK-like cell, TALL-104*** was effective in treating a variety of malignancies in dogs.".

Klingemann was an author of said publication. Thus, contrary to the comments in the Klingemann declaration, Tam et al. disclose that TALL-104 is an NK-like cell line which is similar enough to NK cells that findings using TALL-104 cells can be extrapolated to NK cell lines. Furthermore, Klingemann et al. (1996) also disclose that NK-92 and TALL-104 cells have similar lytic properties (see page 73, first column). In addition, regarding comments in the Klingemann declaration, Gong et al. states in page 657, first column that NK-92 cells require IL-2 for continued growth. Regarding applicants comments about long-felt need, similar cells and methods were already known in the art (aka TALL-104 as per Santoli et al.).

The claimed method is an in vivo method of treatment and there is no evidence of record that in vivo treatment with NK-92 cells is superior to in vivo treatment with TALL-104 cells. Furthermore, the Arai publication supplied with the Klingemann declaration states that their trials were phase I wherein "Efficacy was not determined in this phase I trial ..." (page 631, second column, first complete paragraph).

Furthermore as per above, it would have required nothing more than routine experimentation to create the claimed invention. Furthermore the MPEP section 716.04 states:

716.04 [R-2] Long-Felt Need and Failure of Others

>I. < THE CLAIMED INVENTION MUST SATISFY A LONG-FELT NEED WHICH WAS *RECOGNIZED, PERSISTENT, AND NOT SOLVED BY OTHERS.*

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Primary Examiner, Art Unit 1644

/Ram R. Shukla/
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